

इंटरनेट

मानक

Disclosure to Promote the Right To Information

Whereas the Parliament of India has set out to provide a practical regime of right to information for citizens to secure access to information under the control of public authorities, in order to promote transparency and accountability in the working of every public authority, and whereas the attached publication of the Bureau of Indian Standards is of particular interest to the public, particularly disadvantaged communities and those engaged in the pursuit of education and knowledge, the attached public safety standard is made available to promote the timely dissemination of this information in an accurate manner to the public.

“जानने का अधिकार, जीने का अधिकार”

Mazdoor Kisan Shakti Sangathan

“The Right to Information, The Right to Live”

“पुराने को छोड़ नये के तरफ”

Jawaharlal Nehru

“Step Out From the Old to the New”

IS 12375-3 (1993): Implants for Surgery - Partial and Total Hip Joint Prostheses, Part 3: Determination of endurance properties of stemmed femoral components without application of torsion [MHD 2: Orthopaedic Instruments, Implants and Accessories]



“ज्ञान से एक नये भारत का निर्माण”

Satyanarayan Gangaram Pitroda

“Invent a New India Using Knowledge”



“ज्ञान एक ऐसा खजाना है जो कभी चुराया नहीं जा सकता है”

Bhartrhari—Nitiśatakam

“Knowledge is such a treasure which cannot be stolen”

BLANK PAGE



भारतीय मानक

शल्य चिकित्सा के लिए अन्तर्रोपण – आंशिक और
सम्पूर्ण कुल्हे पर के जोड़

भाग 3 ऐठन रहित अनुप्रयोग के डन्डीनुमा फेमोरल अवयवों के सह्यता
गुणधर्म ज्ञात करना

Indian Standard

IMPLANTS FOR SURGERY — PARTIAL AND TOTAL
HIP JOINT PROSTHESES

PART 3 DETERMINATION OF ENDURANCE PROPERTIES OF STEMMED
FEMORAL COMPONENTS WITHOUT APPLICATION OF TORSION

UDC 616'089'28 : 611'98 : 620'169'1

© BIS 1993

BUREAU OF INDIAN STANDARDS

MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

NATIONAL FOREWORD

This Indian Standard which is identical with ISO 7206-3 : 1988 'Implants for surgery — Partial and total hip joint prostheses : Part 3 Determination of endurance properties of stemmed femoral components without application of torsion', issued by the International Organization for Standardization (ISO), was adopted by the Bureau of Indian Standards on the recommendation of the Orthopaedic Instruments and Accessories Sectional Committee and approval of the Medical Equipment and Hospital Planning Division Council.

The text of above mentioned ISO standard has been approved as suitable for publication as Indian Standard without deviation. Certain conventions are however not identical to those used in the Indian Standards. Attention is particularly drawn to the following:

- a) Wherever the words 'International Standard' appear, referring to this standard, they should be read as 'Indian Standard'.
- b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain international standards for which Indian Standards also exist. The corresponding Indian Standards which are to be substituted in their place are listed below along with their degree of equivalence for editions indicated:

<i>International Standard</i>	<i>Corresponding Indian Standard</i>	<i>Degree of Equivalence</i>
ISO 3696 : 1987	IS 1070 : 1977 Water for laboratory use (<i>second revision</i>)	Technically equivalent
ISO 4965 : 1979	IS 6886 : 1973 Method for dynamic force calibration of axial load fatigue testing machines by means of a strain gauge technique	Technically equivalent
ISO 5833 : 1977	IS 8641 : 1984 Acrylic resin cement for orthopaedic implants (<i>first revision</i>)	Identical
ISO 7601-1 : 1985	IS 12375 (Part 1) : 1987 Partial and total hip joint prostheses : Part 1 Classification, designation of dimensions and requirements	Identical
ISO 7500-1 : 1986	IS 1828 : 1975 Method for load verification of tensile testing machines (<i>first revision</i>)	Technically equivalent

Indian Standard

IMPLANTS FOR SURGERY — PARTIAL AND TOTAL HIP JOINT PROSTHESES

PART 3 DETERMINATION OF ENDURANCE PROPERTIES OF STEMMED FEMORAL COMPONENTS WITHOUT APPLICATION OF TORSION

1 Scope

This part of ISO 7206 describes a test method for determining the endurance properties, under specified laboratory conditions, of stemmed femoral components of total hip joint prostheses and stemmed femoral components used alone in partial hip joint replacement, without the application of torsion. It also defines the conditions of testing so that the important parameters that affect the components are taken into account, and describes how the specimen is set up for testing.

This test method has been developed for prostheses that have a plane of symmetry, and may not be suitable for other designs of prosthesis, e.g. those having preformed anteversion or double curvature of the stem.

This part of ISO 7206 does not cover methods of examining and reporting of the test specimen; these should be agreed between the test laboratory and the party submitting the specimen for test.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 7206. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 7206 are encouraged to investigate the possibility of applying the most recent editions of the standards listed below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 3696 : 1987, *Water for analytical laboratory use — Specifications and test methods*.

ISO 4965 : 1979, *Axial load fatigue testing machines — Dynamic force calibration — Strain gauge technique*.

ISO 5833 : 1979, *Implants for surgery — Acrylic resin cements — Part 1 : Orthopaedic applications*.

ISO 7206-1 : 1985, *Implants for surgery — Partial and total hip joint replacements — Part 1 : Classification, designation of dimensions and requirements*.

ISO 7500-1 : 1986, *Metallic materials — Verification of static uniaxial testing machines — Part 1 : Tensile testing machines*.

3 Definitions

For the purposes of this part of ISO 7206, the definitions given in ISO 7206-1 apply.

4 Principle of the test method

Embedding of the lower portion of the test specimen in a solid medium. Partial immersion of the protruding part of the test specimen in a fluid test medium. Application of a cyclic load to the head of the test specimen until the specimen exhibits failure or until the chosen number of cycles has been attained. Subsequent examination of the specimen for defects caused by the loading regime.

5 Reagents and materials

5.1 Fluid test medium

Solution of analytical grade sodium chloride
[$\rho(\text{NaCl}) = 9 \text{ g/l}$], continuously aerated, in distilled or deionized water of grade 3 as specified in ISO 3696.

5.2 Embedding medium

A casting medium, which should

- a) not be affected by the fluid test medium (5.1);
- b) not crack or break under the load applied during testing;
- c) not exhibit excessive deformation or creep;
- d) be reproducible in strength and other characteristics.

Three media that appear satisfactory are acrylic bone cement (see ISO 5833-1), epoxy casting resin and high-alumina cement (see annex A which contains guidance on a satisfactory composition of high-alumina cement).

6 Apparatus

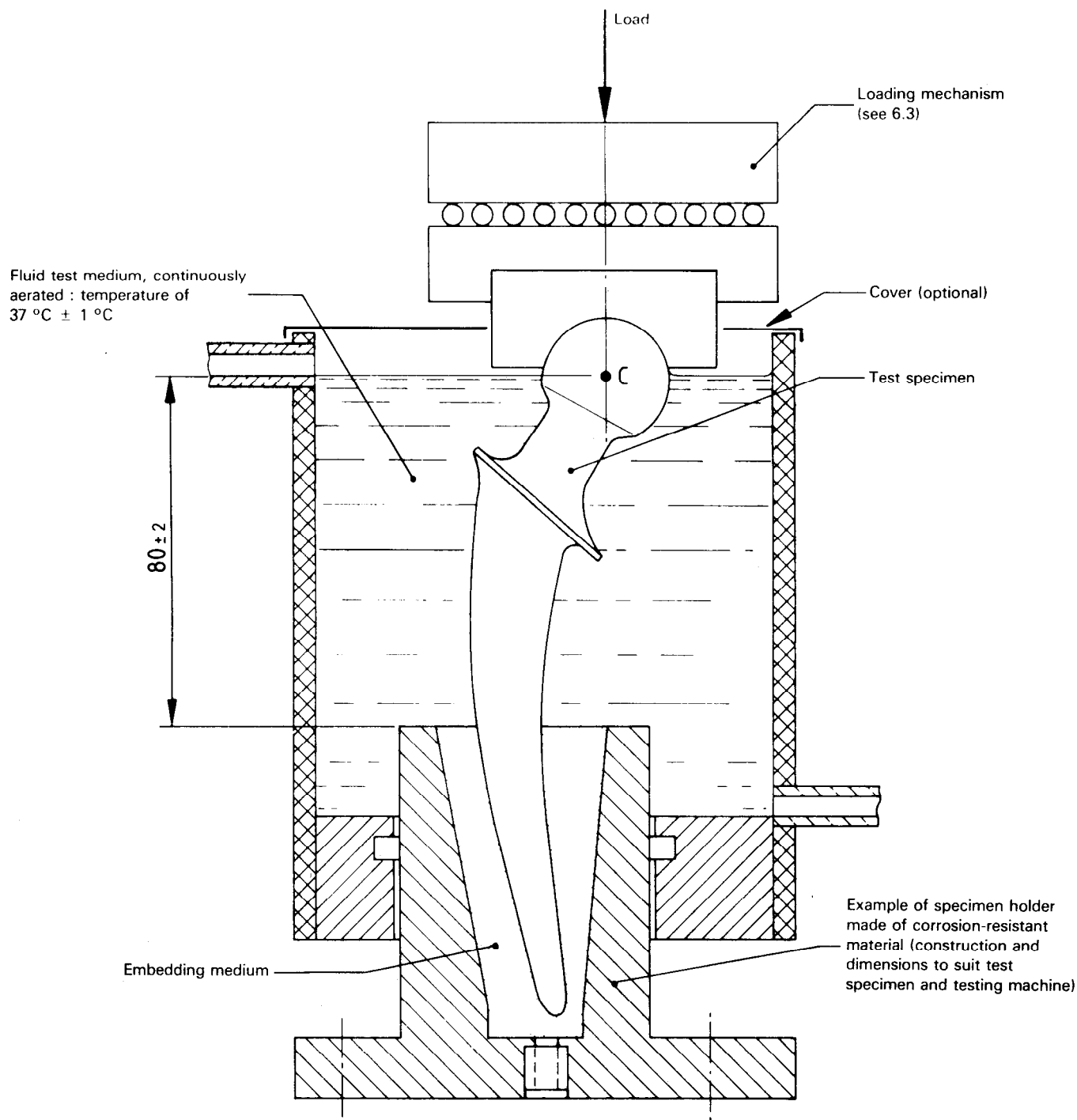
6.1 Testing machine, having the following characteristics :

- error in applied load : not greater than $\pm 1\%$ at maximum load (see ISO 7500-1 and ISO 4965);
- dynamic loading waveform : sinusoidal;
- instrumentation to monitor the values of the maximum

and minimum loads and the deflection of the head of the test specimen to an accuracy of $\pm 2\%$ and to record the number of cycles or the elapsed time of operation.

6.2 Specimen holders, of a corrosion-resistant material and having a construction and dimensions to suit the testing machine and test specimens. An example of a suitable holder is shown in figure 1.

Dimensions in millimetres



NOTE — Point C is designated in ISO 7206-1.

Figure 1 — General arrangement of specimen for testing

6.3 Means of loading the test specimen which maintains loading through the centre of the head of the specimen, parallel to the axis of the testing machine, and which incorporates a low-friction mechanism that minimizes loads not parallel to the axis of the testing machine.

NOTE — Attention is drawn to the importance of lubricating the loading mechanism correctly.

6.4 Means of continuously aerating the fluid test medium, e.g. a small air pump of the type used for aquaria.

6.5 Means of maintaining the temperature of the fluid test medium at $37\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$.

6.6 Means of maintaining constant composition of the fluid test medium, e.g. by continual replenishment from a reservoir.

6.7 Device to grip the test specimen by the head or neck, which retains the specimen in any desired orientation. An example of a suitable device to grip the head of the specimen is shown in figure 2.

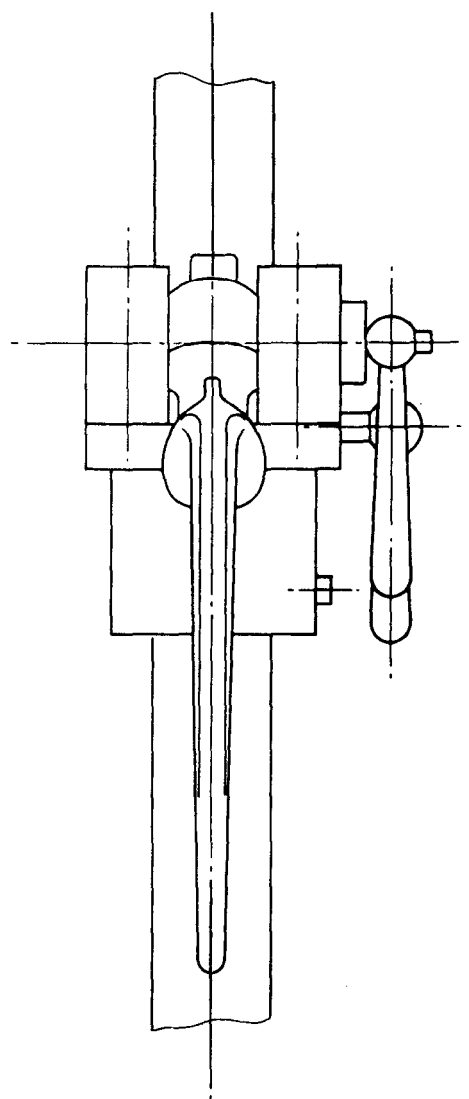
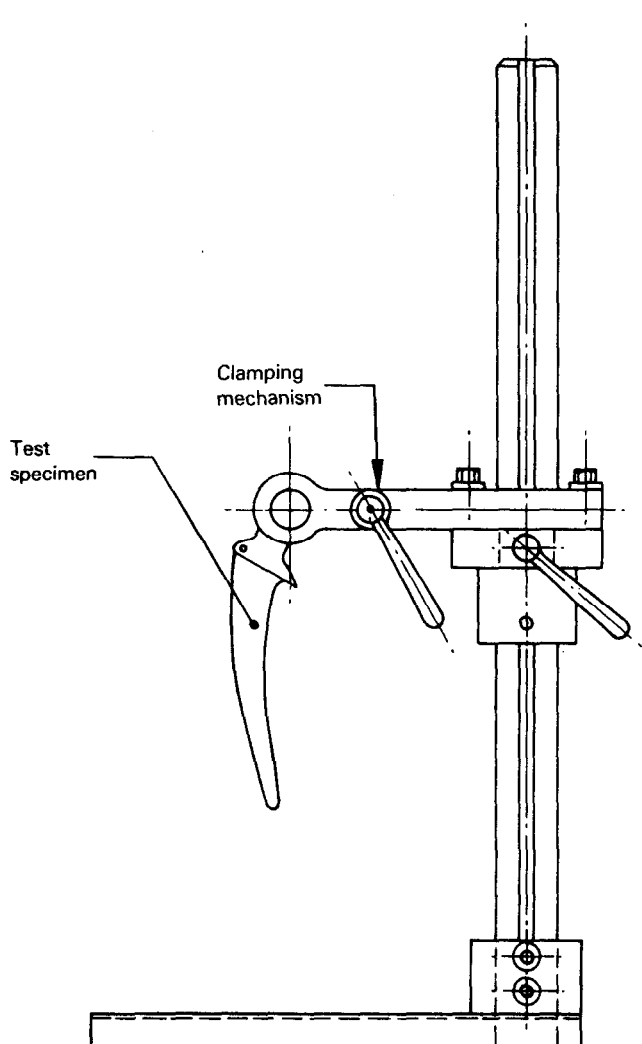


Figure 2 — Example of a device for gripping the head of the test specimen during setting-up (see 6.7)

7 Procedure

7.1 Hold the head or neck of the test specimen by means of the gripping device (6.7) and position the specimen so that axis KL of the stem, as designated in figure 3, is inclined at an angle of 10° to the vertical. An example of a technique that may be used for setting the specimen in the correct orientation is given in annex B.

NOTE — It is essential that the neck of the prosthesis is not marked or damaged during this process because damage can affect the endurance properties. Damage to the head of the prosthesis should also be avoided as this can increase the friction between the head and the loading system during testing.

7.2 Embed the specimen in the embedding medium (5.2) in the holder (6.2) so that the upper surface of the medium is at a distance of 80 mm ± 2 mm vertically below the centre of the head of the prosthesis (point C as defined in ISO 7206-1). Take care not to mark or otherwise damage the stem.

7.3 Support the test specimen in position until the embedding medium has hardened sufficiently to support the specimen unaided. Do not start testing until the embedding medium has hardened fully.

7.4 Mount the holder and embedded specimen in the testing machine (6.1) so that the load line of the testing machine intersects point C of the specimen, as defined in ISO 7206-1. Clamp the holder firmly in position and ensure that the correct orientation of the specimen is maintained. Measure and record the head offset length, as designated in figure 3.

7.5 Partially immerse the specimen in the fluid test medium (5.1) so that the surface of the liquid is approximately level with the centre of the head of the test specimen. Maintain the aeration, temperature and composition of the fluid test medium by the appropriate means (see 6.4 to 6.6).

7.6 Start the testing machine and adjust it so that the desired load range is applied to the test specimen through the loading mechanism (6.3).

NOTE — The minimum load necessary for satisfactory operation of the testing machine has been found to be a force between 200 N and 300 N.

7.7 Operate the testing machine at a chosen frequency of between 1 Hz and 10 Hz.

NOTE — A frequency of 1 Hz is recommended for testing non-metallic specimens; a frequency of 10 Hz is recommended for testing metallic specimens.

7.8 Set the testing machine or other instrument to give an indication if the vertical or horizontal component of the specimen deflection exceeds a preset value approximately 25 % greater than the deflection occurring in the first minute of running at test load.

If this indication is given by the testing machine or the instrument, terminate the test. Examine the embedding medium and the specimen to determine whether the specimen has loosened in the embedding medium or yield of the specimen has occurred.

7.9 Continue the test until one of the following events occurs :

- a) yield or loosening, as described in 7.8;
- b) fracture of the specimen;
- c) registration of completion of the chosen number of load cycles.

In each case, record the number of cycles.

7.10 Remove the specimen from the embedding medium.

7.11 Examine the test specimen, using the methods requested by the party that submitted the specimen for testing.

8 Test report

The test report shall include the following information :

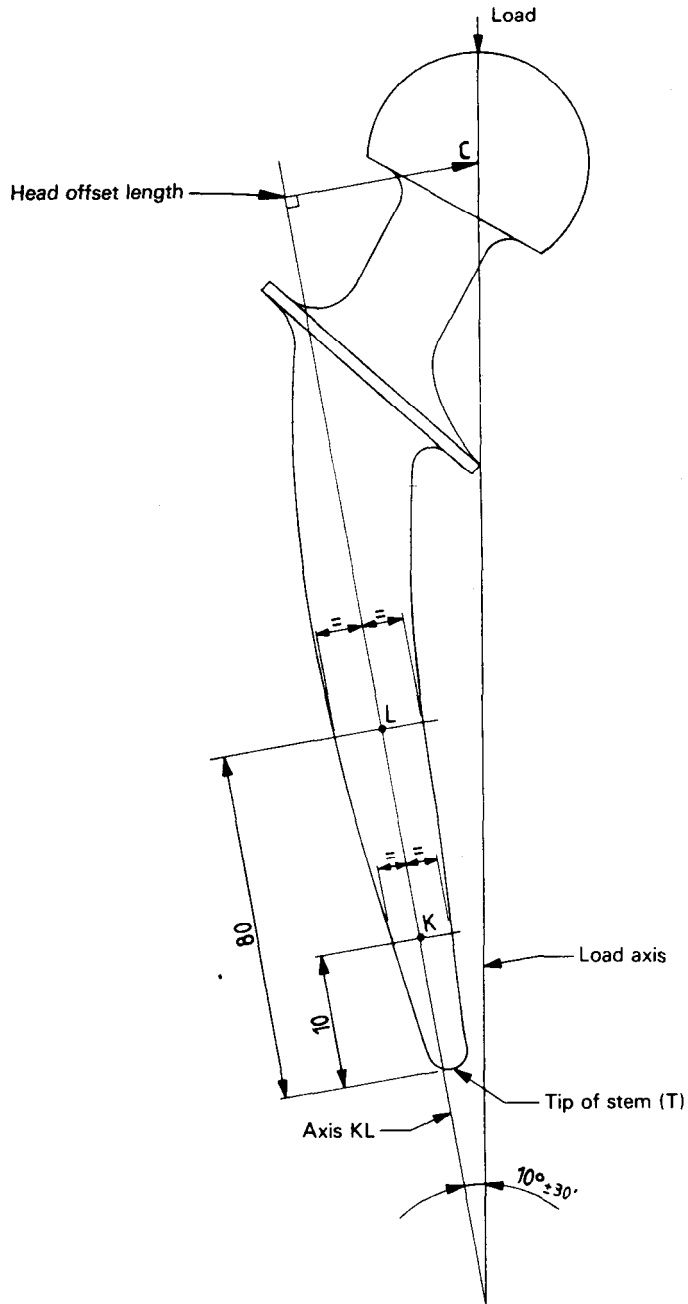
- a) a reference to this part of ISO 7206;
- b) the identity of the test specimen, as stated by the party submitting the specimen for test;
- c) the embedding medium used;
- d) the minimum and maximum loads applied;
- e) the duration of the test, in cycles;
- f) the loading frequency;
- g) the head offset length, as designated in figure 3;
- h) a statement of results, including location of fracture (if applicable), description of test specimen at the end of the test, and the results of the examination requested by the party submitting the specimen for test;
- i) a record of if and why the test was terminated.

9 Disposal of test specimens

It is imperative that the prosthesis should not be used for clinical purposes after testing.

Care should be exercised in the use of the specimen for further mechanical tests because the loading regime may have altered the mechanical properties. In particular, it is recommended that the specimen is not used for further endurance testing.

Dimensions in millimetres



NOTE — Point C is as designated in ISO 7206-1. The orientation and reference points shown are for use with test specimens with and without a plateau.

Figure 3 — Orientation of specimen under test

Annex A
(informative)

Guidance on composition of high-alumina cement embedding medium

The composition given in table A.1 has been found to be satisfactory. If a different brand of cement is used, the manufacturer should be consulted for details of the composition and process that will yield a medium of maximum strength.

The solids should be mixed dry. Water should then be added on a compacting table and the medium mixed until air bubbles cease to rise to the surface.

The composition given in table A.1 requires approximately 7 days at room temperature to achieve maximum strength. This period may differ for different brands of cement.

Table A.1 — Composition of high-alumina cement embedding medium

Constituent	Parts by mass
Granite chips ¹⁾ having a major diameter of approximately 5 mm	4
Builder's sharp sand	4
High-alumina cement ²⁾	2
Water	1
Total	11
<p>1) The type known as "Mount Sorrel"*) has been found to be satisfactory.</p> <p>2) It may be noted for information that the type known as "Lightning"*) manufactured by the Blue Circle Company has been found to be satisfactory, but any other high-alumina cement may also be used.</p>	

*) This information is given for the convenience of users of this part of ISO 7206 and does not constitute an endorsement by ISO of the product named. Equivalent products may be used if they can be shown to lead to the same results.

Annex B (informative)

Example of a method for setting up a specimen for testing

B.1 Principle

Use of a jig, having dimensions based on those of the resected human femur, to establish the correct orientation of the test specimen and to facilitate embedding.

B.2 Apparatus

B.2.1 Jig, having the dimensions shown in figure B.1, made of corrosion-resistant material.

B.2.2 Device for gripping the specimen, which allows adjustment of the position of the specimen, as shown in figure B.2.

B.2.3 Specimen holder, consisting of two parts : one to contain the embedding medium and test specimen, and the other to contain the fluid test medium, as shown in figure 1.

B.3 Reagents and materials

Reagents and materials as specified in clause 5.

B.4 Procedure

B.4.1 Place the test specimen in the jig (B.2.1) so that the axis KL of the stem (as defined in figure 3) is coincident with

the axis of the jig that represents the axis of the normal femur, and so that the plateau, or the intersection of the underside of the neck and the medial surface of the stem, rests on the top surface of the jig.

Care should be taken to avoid damaging or marking the stem of the prosthesis.

B.4.2 Grip the head in the gripping device (B.2.2). Remove the jig, thus leaving the test specimen in the correct orientation for testing.

B.4.3 Introduce an appropriate amount of embedding medium (5.2) into the specimen holder (B.2.3), and place the holder in position underneath the test specimen.

B.4.4 Slowly lower the test specimen so that the stem enters the embedding medium to the correct depth, as shown in figure B.2. Allow the embedding medium to harden.

B.4.5 Release the head of the test specimen from the gripping device and place the holder and embedded test specimen in the testing machine (6.1). Attach the container for the fluid test medium (see figure 1).

B.4.6 Start testing as described in 7.5.

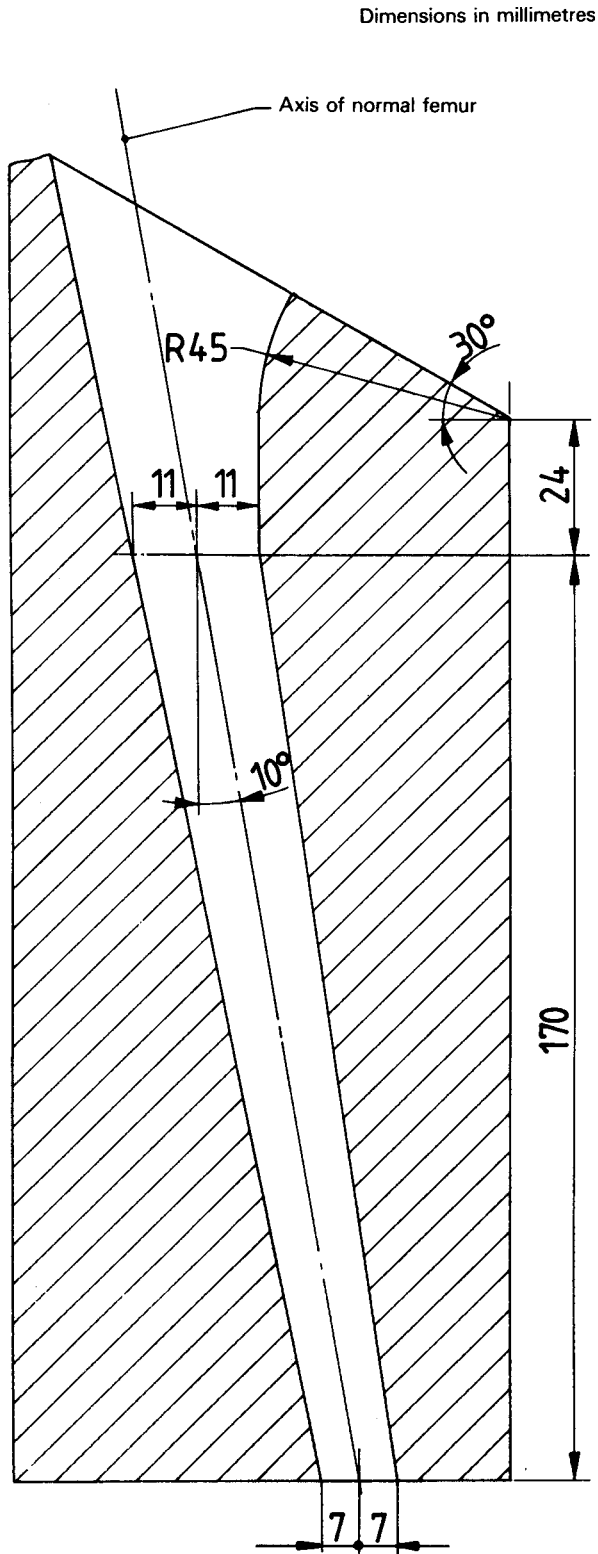


Figure B.1 — Jig for establishing orientation of test specimen

Dimensions in millimetres

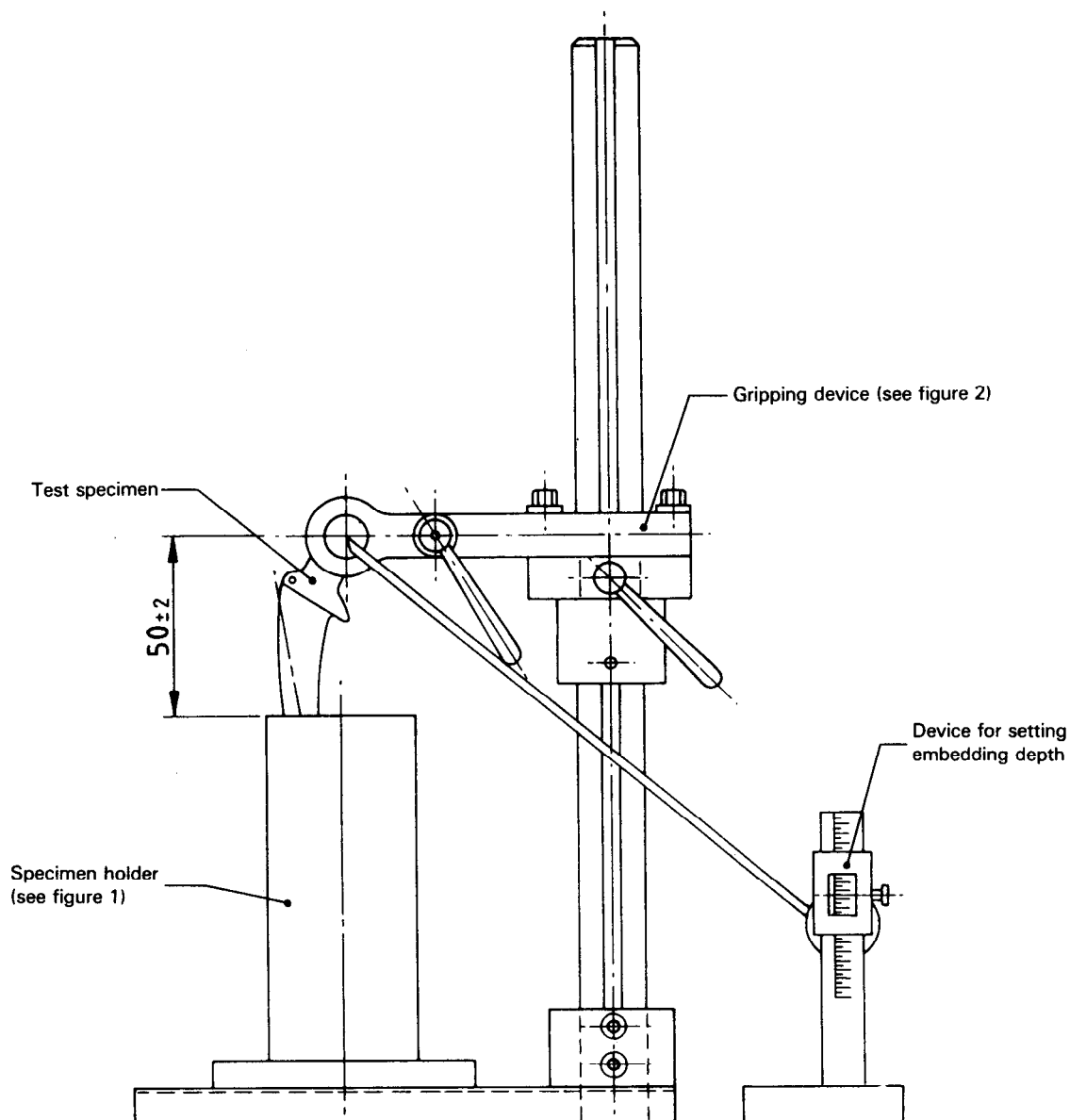


Figure B.2 — Apparatus for gripping test specimen and for embedding it in the correct orientation

Standard Mark

The use of the Standard Mark is governed by the provisions of the *Bureau of Indian Standards Act, 1986* and the Rules and Regulations made thereunder. The Standard Mark on products covered by an Indian Standard conveys the assurance that they have been produced to comply with the requirements of that standard under a well defined system of inspection, testing and quality control which is devised and supervised by BIS and operated by the producer. Standard marked products are also continuously checked by BIS for conformity to that standard as a further safeguard. Details of conditions under which a licence for the use of the Standard Mark may be granted to manufacturers or producers may be obtained from the Bureau of Indian Standards.

Bureau of Indian Standards

BIS is a statutory institution established under the *Bureau of Indian Standards Act, 1986* to promote harmonious development of the activities of standardization, marking and quality certification of goods and attending to connected matters in the country.

Copyright

BIS has the copyright of all its publications. No part of these publications may be reproduced in any form without the prior permission in writing of BIS. This does not preclude the free use, in the course of implementing the standard, of necessary details, such as symbols and sizes, type or grade designations. Enquiries relating to copyright be addressed to the Director (Publications), BIS.

Revision of Indian Standards

Amendments are issued to standards as the need arises on the basis of comments. Standards are also reviewed periodically; a standard along with amendments is reaffirmed when such review indicates that no changes are needed; if the review indicates that changes are needed, it is taken up for revision. Users of Indian Standards should ascertain that they are in possession of the latest amendments or edition by referring to the latest issue of 'BIS Handbook' and 'Standards Monthly Additions'. Comments on this Indian Standard may be sent to BIS giving the following reference:

Doc : No MHD 02 (2354)

Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

BUREAU OF INDIAN STANDARDS

Headquarters:

Manak Bhavan, 9 Bahadur Shah Zafar Marg, New Delhi 110002
Telephones : 331 01 31, 331 13 75

Telegrams : Manaksanstha
(Common to all Offices)

Regional Offices :

Central : Manak Bhavan, 9 Bahadur Shah Zafar Marg
NEW DELHI 110002

Telephone

{ 331 01 31
{ 331 13 75

Eastern : 1/14 C. I. T. Scheme VII M, V. I. P. Road, Maniktola
CALCUTTA 700054

{ 37 84 99, 37 85 61
{ 37 86 26, 37 86 62

Northern : SCO 445-446, Sector 35-C, CHANDIGARH 160036

{ 53 38 43, 53 16 40
{ 53 23 84

Southern : C. I. T. Campus, IV Cross Road, MADRAS 600113

{ 235 02 16, 235 04 42
{ 235 15 19, 235 23 15

Western : Manakalaya, E9 MIDC, Marol, Andheri (East)
BOMBAY 400093

{ 632 92 95, 632 78 58
{ 632 78 91, 632 78 92

Branches : AHMADABAD. BANGALORE. BHOPAL. BHUBANESHWAR. COIMBATORE.
FARIDABAD. GHAZIABAD. GUWAHATI. HYDERABAD. JAIPUR. KANPUR.
LUCKNOW. PATNA. THIRUVANANTHAPURAM.